

Clostridium Perfringens Type A Toxoid

For use in healthy cattle as an aid in the control of disease syndromes caused by the alpha toxin of *Clostridium perfringens* Type A.

- **Aids in the control of disease syndromes caused by the alpha toxin of *Clostridium perfringens* Type A** — *Clostridium perfringens* Type A is implicated in serious and often deadly diseases, such as hemorrhagic bowel syndrome in mature dairy and beef cows. *Clostridium perfringens* Type A also is deadly in calves and is commonly isolated in cases where abomasal ulcers, abomasal hemorrhage and abdominal tympany are found.
- **The first conditionally licensed *C. perfringens* Type A vaccine for cattle** — The vaccine surpassed USDA requirements, producing double the level of international antitoxin units per mL required by the USDA.¹
- **University research shows immune response of cows, calves** — Colorado State University researchers found that **Clostridium Perfringens Type A Toxoid** administered during the dry period led to increased anti-alpha toxin antibody in cows, as well as increased levels in their colostrum-fed calves.²
- **Field studies demonstrate product safety** — Studies involving 867 dairy and beef cattle – both open and pregnant—of various ages and breeds demonstrated the product is safe when used according to label directions.
- **Type A protection that seven-way vaccines don't have** — Standard clostridial seven-way vaccines don't offer protection against the alpha toxin of *C. perfringens* Type A, nor is there any evidence of cross protection.
- **Contains a proprietary dual-component adjuvant system** — For optimum immune response and low tissue impact.

Product Numbers

Clostridium Perfringens Type A Toxoid

#363 – 20 mL-10 doses
#364 – 100 mL-50 doses



Clostridium Perfringens Type A Toxoid

ADJUVANT: Proprietary dual component

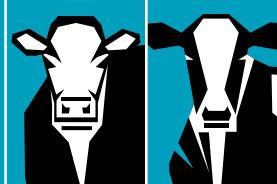
DIRECTIONS: Shake well before using. Administer 2 mL subcutaneously. In accordance with Beef Quality Assurance guidelines, this product should be administered subcutaneously (under the skin) in the neck. Revaccinate in 2 – 4 weeks. Calves vaccinated prior to 5 months of age should be revaccinated at 5 – 6 months of age. Revaccinate annually or as recommended by your veterinarian.

PRECAUTIONS: Store out of direct sunlight at 2° – 7° C (35° – 45° F). DO NOT FREEZE. Use entire contents when first opened. Do not vaccinate within 21 days prior to slaughter. Safety has been demonstrated in animals as young as 1 month of age. Transient swelling may occur at the site of injection. This product has demonstrated a reasonable expectation of efficacy in 5-month of age calves. This product is conditionally licensed by the USDA while additional efficacy and potency data are being developed. Anaphylactic reactions may occur. Symptomatic treatment: Epinephrine.



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Technical disease information

Clostridium perfringens Type A is implicated in serious and often deadly gastrointestinal diseases that can cause sudden death of dairy and beef cows and calves.

Research demonstrates that *C. perfringens* Type A is associated with:

- **Hemorrhagic bowel syndrome (HBS) in mature cows** — HBS strikes apparently healthy cows without much warning, and has an estimated fatality rate of 85 percent or higher within the first 24 – 36 hours. It is more prevalent in dairy cows, but it has also been reported in beef cattle.
- **Abomasal ulcers, abomasal hemorrhage and abdominal tympany in calves** — Beef and dairy calves show signs of quick onset of abdominal distention with pain, bloat, depression, feed refusal and sudden death. While there is more than one cause, researchers have isolated *C. perfringens* Type A from affected calves in several studies.³

HBS: An Emerging Threat

C. perfringens Type A has been detected in 85 percent of HBS cases.⁴ Also known as “bloody gut” or “jejunal hemorrhage syndrome,” HBS causes blood clots in the intestines, leading to enlarged and/or obstructed bowels. Animals may be individually affected, but there’s often a cluster of several cases within a single herd or geographic region. Clinical signs include:

- Sudden death
- Sudden and complete anorexia
- Severe decrease in milk production
- Colic
- Severe depression
- Blood clots in feces
- Distended abdomen

Because medical and surgical treatment measures often fail, prevention and management strategies are critical. Novartis Animal Health manufactured custom (autogenous) vaccines for *C. perfringens* Type A for several years, and veterinarians reported favorable results.

Clostridium Perfringens Type A Toxoid from Novartis Animal Health is the first commercial product for cattle to receive a conditional license by the USDA to aid in the control of disease syndromes caused by the alpha toxin of *C. perfringens* Type A. The product can be given to pregnant or nonpregnant animals.

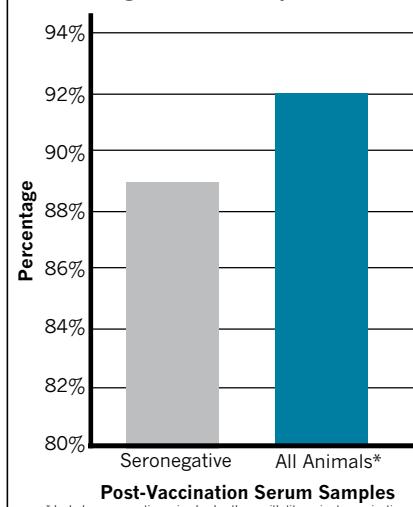
Vaccine Surpasses USDA Requirements

To receive a USDA conditional license, the ***Clostridium Perfringens Type A Toxoid*** had to pass a USDA standardized test. The test requires that a reasonable expectation of efficacy be demonstrated by the development of a serum antibody concentration of at least 4 international antitoxin units per mL in at least 80 percent of vaccinated animals that were seronegative prior to vaccination.

Test results demonstrated that using the ***Clostridium Perfringens Type A Toxoid*** vaccine resulted in 8 international antitoxin units per mL in 89 percent of vaccinated calves that were seronegative prior to vaccination.¹ This means the level of circulating antitoxin in the blood was double that required by the USDA.

In addition, the seroconversion rate in calves receiving the vaccine was 92 percent if calves with a prevaccination titer of more than 1 international antitoxin units per mL are included.¹ (See Figure 1.)

Figure 1. Percentage of Animals Reaching Minimum Requirements

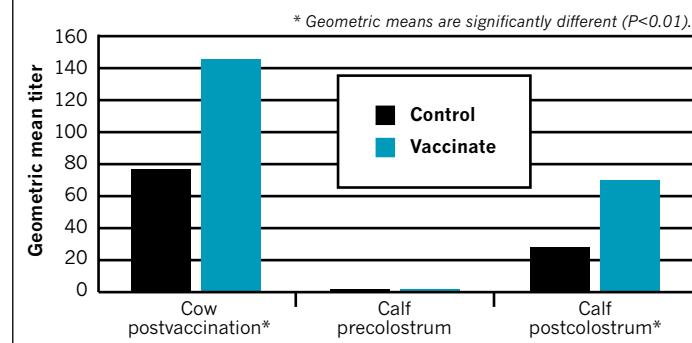


* Includes seronegative animals plus those with titer prior to vaccination.

C. perfringens Type A vaccination

Researchers at Colorado State University studied the effect that vaccinating with ***Clostridium Perfringens Type A Toxoid*** has on pregnant cows and heifers, and their offspring, through colostrum.² Results found that the vaccine administered during the dry period led to increased anti-alpha toxin antibody in cows, as well as increased levels in their colostrum-fed calves.² (See Figure 2.)

Figure 2: Alpha Toxin Titer Results After Vaccination With *Clostridium Perfringens Type A Toxoid*



1. ***Clostridium Perfringens Type A Toxoid***. Code 8081.00. Report 1. Cattle Immunogenicity. Novartis Animal Health US, Inc. Feb. 3, 2004.

2. Van Metre D. Passive transfer of neutralizing antibodies to *Clostridium perfringens* Type A alpha toxin in dairy calves fed colostrum from immunized dams. Paper presented at Annual Meeting of American Association of Bovine Practitioners 2006; Saint Paul, Minnesota.

3. McGuirk S. Managing Clostridial Diseases in Cattle, in *Proceedings*. 2002 Midwest Dairy Herd Health Conference.

4. Dennison AC, Van Metre DC, Callan RJ, et al. Hemorrhagic bowel syndrome in dairy cattle: 22 cases (1997-2000). *J Am Vet Med Assoc* 2002;221:686-689.